510(K) SUMMARY

SUBMITTER INFORMATION

A.	Company Name:	IntraLuminal Therapeutics, Inc.
B.	Company Address:	6354 Corte Del Abeto – Suite A Carlsbad, CA 92009
C.	Company Phone:	(760) 918-1820
D.	Company Facsimile:	(760) 603-9615
E.	Contact Person:	Pamela Misajon Vice President of Regulatory Affairs and Quality Assurance

DEVICE IDENTIFICATION

A.	Device Trade Name:	ILT 0.014" Catheter
B.	Catalog Number:	C114NL2
C.	Device Common Name:	Percutaneous Catheter
D.	Classification Name:	Percutaneous Catheter
E.	Device Class:	Class II (per 21 CFR 870.1250)

IDENTIFICATION OF PREDICATE DEVICE

The ILT 0.014" Catheter is similar in design, materials, mode of operation and intended use to the Medtronic Buchbinder Envoy Percutaneous Catheters cleared for commercial distribution under 510(k) K935425.

DEVICE DESCRIPTION

The ILT 0.014" Catheter is a single-lumen intravascular catheter intended for percutaneous use. It is designed to be used in conjunction with a steerable guidewire to gain access to locations within the cardiovascular system that are remote from the site of insertion. Once accessed, guidewires may be exchanged within the catheter. The ILT 0.014" Catheter may also be used for infusion of saline based solutions through the single lumen by use of the infusion port on the catheter handle.

The ILT 0.014" Catheter is comprised of two components:

1. A single lumen catheter shaft that is inserted percutaneously into the patient vasculature. This component is intended to make contact with the patient's circulating blood stream.
2. A handle that provides torque control to the user. The handle includes an internal mechanism for incremental advancement of the guide wire. The handle does not make contact with the patient.

The effective length of the ILT 0.014" Catheter is a nominal 129cm (50.78"). The nominal maximum outside diameter is 2.8 French (0.037"). A radiopaque marker is located on the distal tip of the catheter to aid in visualization under fluoroscopy. The inside diameter of the ILT 0.014" Catheter shaft will accommodate a commercially available 0.014" guide wire. The guidewire can be inserted into the catheter shaft lumen through an access aperture in the base of the handle. The catheter handle includes an advancing mechanism that allows for incremental advancement of the guide wire (nominal 0.25mm per click of the catheter handle thumbwheel). This mechanism may be bypassed for rapid large movements of the guidewire through the catheter shaft.

The ILT 0.014" Catheter is packaged in a Tyvek® Pouch and heat-sealed to form a sterile barrier. The packaged catheter is sterilized by ethylene oxide gas. The packaged catheter is provided "STERILE" and Non-pyrogenic, and is intended for single use only.

INTENDED USE

The ILT 0.014" Catheter is indicated to be used in conjunction with a steerable guide wire in order to access discreet regions of the vasculature. Once the region has been accessed, an exchange of one guide wire for another can occur. The ILT 0.014" Catheter may also be used to provide a conduit for the delivery of saline solutions or diagnostic contrast agents.

TECHNOLOGICAL CHARACTERISTICS

The ILT 0.014" Catheter is similar in basic materials, design, construction and mechanical performance to the predicate device.

BIOCOMPATIBILITY AND PERFORMANCE DATA

Biocompatibility testing and *in vitro* bench studies were conducted to evaluate the biological and performance characteristics of the ILT 0.014" Catheter. Biocompatibility test results indicate that the device materials are biocompatible. Performance test results indicate that the device satisfies functional performance requirements when used as indicated.

CONCLUSIONS DRAWN FROM STUDIES

The results of testing demonstrate that the ILT 0.014" Catheter is substantially equivalent to the predicate device and is capable of safely and accurately performing the stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 25 2000

Ms. Pamela Misajon
IntraLuminal Therapeutics, Inc.
6354 Corte Del Abeto, Suite A
Carlsbad, CA 92009

Re: K001992
ILT 0.014" Catheter
Regulatory Class: II (two)
Product Code: 74 DQY
Dated: June 28, 2000
Received: June 29, 2000

Dear Ms. Misajon:

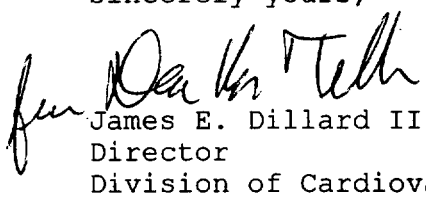
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: To Be Assigned By FDA

Device Name: ILT 0.014" Catheter

Indications For Use: The ILT 0.014" Catheter is indicated to be used in conjunction with a steerable guidewire in order to access discreet regions of the vasculature. Once the region has been accessed, an exchange of one guidewire for another can occur. The ILT 0.014" Catheter may also be used to provide a conduit for the delivery of saline solutions or diagnostic contrast agents.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K001992